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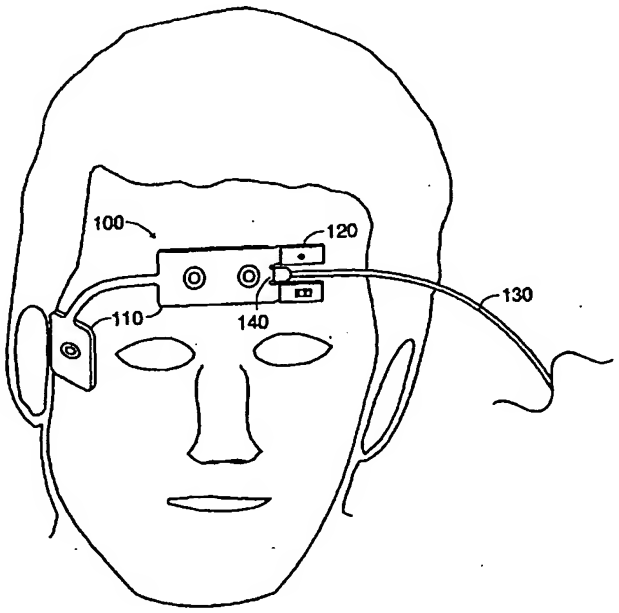
(54) Title: PHYSIOLOGICAL SENSOR COMBINATION



(57) Abstract: A physiological sensor combination has a flexible substrate configured to attach to a tissue site. Multiple sensors are disposed on the substrate, which generate physiological signals. Each of the signals is responsive to a different physiological parameter. Conductors are carried on the substrate and routed between the sensors and at least one connector. The connector is configured to communicate the physiological signals to at least one monitor, which derives measurements of the parameters.

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PHYSIOLOGICAL SENSOR COMBINATION

BACKGROUND OF THE INVENTION

Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of a person's oxygen supply. Early detection of low blood oxygen level is important in the medical field, for example in critical care and surgical applications, because an insufficient supply of oxygen can result in brain damage and death in a matter of minutes. A pulse oximetry system consists of a sensor applied to a patient, a pulse oximeter, and a patient cable connecting the sensor and the pulse oximeter. The pulse oximeter typically provides a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indication of each pulse. In addition, the pulse oximeter may display the patient's plethysmograph, which provides a visual indication of the patient's pulse contour and pulse rate.

Measuring a biopotential signal, such as an electroencephalogram (EEG) is also a widely accepted procedure for patient monitoring and diagnostic tests. An EEG measures cortical activity of the brain, which can reflect changes in cortical or subcortical cellular function due to insufficient oxygen or drugs, to name a few. For example, changes in EEG bandwidth and power can provide a measure of the effects of anesthetics on the brain. A biopotential measurement system consists of a bipotential sensor, a monitor and a patient cable connecting the sensor to the monitor. For example, an EEG monitor measures the potential difference between at least two well-spaced electrodes, using a separate ground electrode, and displays the resulting signal.

SUMMARY OF THE INVENTION

A physiological sensor combination has a flexible substrate configured to attach to a tissue site. Multiple sensors are disposed on the substrate, which generate physiological signals. Each of the signals is responsive to a different physiological parameter. Conductors are carried on the substrate and routed between the sensors and at least one connector. The connector is configured to communicate the physiological signals to at least one monitor, which derives measurements of the parameters. In one embodiment, the sensors comprise multiple electrodes disposed on the substrate. Each of the electrodes are adapted to be in electrical communication with the tissue site and electrically connect to at least one of the conductors. Further, an emitter and a detector are mounted to the substrate and electrically connected to at least one of the conductors. The emitter is adapted to transmit light into the tissue site, and the detector is adapted to receive reflected light from the tissue site.

In a particular embodiment, the substrate has a first side adapted to face toward the tissue site and a second side adapted to face away from the tissue site, where the conductors and the electrodes are disposed on the first side and the emitter and the detector are mounted to the first side. The substrate may comprise a fold-over portion having a circuit side corresponding to the first side, where the fold-over portion is adapted to

fold so that the circuit side is proximate the second side. Further, the emitter and the detector may be mounted to the a fold-over portion. The substrate may define at least one aperture configured so that the emitter and the detector each align with a corresponding aperture when the fold-over is in a folded position.

In another particular embodiment, the physiological sensor combination comprises a plurality of biopotential sensor pinouts corresponding to the electrodes, a plurality of optical sensor pinouts corresponding to the emitter and the detector, and a common connector extending from the substrate. The biopotential sensor pinouts and said optical sensor pinouts are each disposed on the common connector.

Another aspect of a physiological sensor combination is a substrate means for combining a first sensor and a second sensor, a connector means for communicating signals from the first sensor and the second sensor to at least one monitor, and an identifying means of conveying information about each of the first sensor and the second sensor to the monitor. The physiological sensor combination may further comprise a fold-over means for positioning sensor components so as to extend away from a tissue site. The physiological sensor combination may additionally comprise an aperture means for providing light communications between sensor components and the tissue site.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of a physiological sensor combination applied to a patient and having a patient cable connected near the patient's forehead;

FIG. **2** is an illustration of a physiological sensor combination applied to a patient and having a patient cable connected near the patient's temple;

FIGS. **3A-B** are perspective views of a circuit substrate and an assembled sensor, respectively, for a physiological sensor combination having a single-sided circuit substrate and a shared connector;

FIG. **4** is a schematic diagram of a physiological sensor combination showing the location of applied sensor components;

FIG. **5** is a layout diagram of a single-sided circuit for a physiological sensor combination;

FIG. **6** is a perspective view of a physiological sensor combination having a single-sided circuit substrate and dual connectors; and

FIG. **7** is a perspective view of a physiological sensor combination having a double-sided circuit substrate and dual connectors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. **1-2** show a physiological sensor combination applied to a patient. FIGS. **3-5** illustrate a physiological sensor combination having a biopotential sensor and an optical sensor configured on a single-sided flexible circuit substrate with a shared patient cable connector. FIG. **6** illustrates a physiological sensor combination also having a biopotential sensor and an optical sensor configured on a single-sided flexible circuit substrate. The biopotential sensor and the optical sensor, however, each have separate patient cable

connectors. FIG. 7 illustrates a physiological sensor combination having a biopotential sensor and an optical sensor configured on a double-sided circuit substrate, each sensor also having separate patient cable connectors.

FIGS. 1-2 illustrate a physiological sensor combination applied to the forehead and temple areas of a patient. A patient cable **130** connects the physiological sensor combination **100** (FIG. **1**), **101** (FIG. **2**) to one or more monitoring devices (not shown). As shown in FIG. **1**, the patient cable **130** may connect near the patient's forehead. As shown in FIG. **2**, the patient cable **130** may alternatively connect near the patient's temple. The biopotential sensor **110** and optical sensor **120** may share a common connector 140. Alternatively, the biopotential sensor **110** and optical sensor **120** may each have a dedicated patient cable connector, as described in further detail with respect to FIGS. **6-7**, below. The biopotential sensor **110** may be an EEG sensor for depth of consciousness monitoring, as described above. The optical sensor **120** may be a pulse oximetry reflectance sensor for oxygen saturation monitoring, also described above

FIGS. **3A-B** illustrate a physiological sensor combination **100** having a biopotential sensor **110** and an optical sensor **120** configured on a flexible circuit substrate **500**. As shown in FIG. **3A**, the flexible circuit **500** is single-sided, having a blank side **501** and a circuit side **502** with printed conductive traces **510** on the circuit side **502**. The biopotential sensor **110** has electrodes **410** (not visible and shown as dashed lines) printed on the circuit side **502**. The electrodes **410** are configured so that one electrode is applied to the temple area and two electrodes are applied to the forehead, as further described with respect to FIGS. **4-5**, below.

Further shown in FIG. **3A**, the optical sensor **120** includes a fold-over **540**, an emitter **420**, a detector **430** and an information element **440**. The emitter **420**, detector **430** and information element **440** are each mounted to the circuit side **502** on the fold-over **540** and electrically connected to traces **510**, as described in detail with respect to FIGS. **4-5**, below. The optical sensor **120** is configured so that emitter **420** and a detector **430** are applied over the forehead, also described with respect to FIGS. **4-5**, below. The fold-over **540** is such that each of the emitter **420** and detector **430** align with corresponding apertures **520** (FIG. **5**) so that light transmitted from the emitter **420** passes through an aperture **520** (FIG. **5**) and into a patient's skin and that reflected light passes out of a patient's skin, through an aperture **520** (FIG. **5**) and is received by the detector **430**. The substrate **500** has a stub **530** that contains pinouts **532** (FIG. **5**), which connect to the electrodes **410** and also to the emitter **420**, detector **430** and information element **440**, also described in detail with respect to FIGS. **4-5**, below. Emitters and a detector for a pulse oximetry sensor are described in detail in US Patent No. 6,256,523 entitled "Low Noise Optical Probe," which is assigned to Masimo Corporation and incorporated by reference herein. An information element for a pulse oximetry sensor is described in detail in US Patent No. 6,001,986 entitled "Manual And Automatic Probe Calibration," which is assigned to Masimo Corporation and incorporated by reference herein.

As shown in FIG. 3B, the biopotential sensor **110** has an adhesive foam layer **310** disposed around the electrodes **410** on the circuit side **502**. The foam layer **310** has an adhesive for patient skin attachment and cushions the biopotential sensor **110** against the skin. Further, the foam layer **310** forms cavities around the electrodes **410** that are filled with a conductive gel for electrical communication between a tissue site and the electrodes **410**. Printed electrode indicators **370** facilitate sensor application on a tissue site. Electrodes printed on a substrate, an associated foam layer, and gel-filled foam cavities are described in detail in US Patent No. 6,032,064 entitled "Electrode Array System For Measuring Electrophysiological Signals," assigned to Aspect Medical Systems, Inc. and incorporated by reference herein. One of ordinary skill in the art will recognize that various electrode configurations may be utilized as the biopotential sensor **110**.

Also shown in FIG. 3B, the optical sensor **120** has a face tape **330** and a base tape **340** that envelop the fold-over **540** along with the fold-over mounted components **420-440**. In one embodiment, the face tape **330** and base tape **340** attach together and to the fold-over **540** with PSA. Further, the base tape **340** has a backing (not shown) that is removed to expose an adhesive for skin attachment. The face tape **330** also secures the detector **430** within an optical cavity and cover **350**. A printed emitter indicator **390** facilitates sensor application on a tissue site. Emitters, detectors, optical cavities and corresponding covers are described in detail in US Patent No. 6,256,523, referenced above.

Further shown in FIG. 3B, the physiological sensor combination **100** has a tab **320** that attaches to the stub **530** (FIG. 3A) to complete the connector **140**. In one embodiment, the attachment is accomplished with pressure sensitive adhesive (PSA) between the tab **320** and stub **530**. The tab **320** provides a stiffener for the pinouts **532** (FIG. 5) and an insertion and locking mechanism for a mating patient cable connector, as described in US Patent No. 6,152,754 entitled "Circuit Board Based Cable Connector" and US Patent No. 6,280,213 entitled "Patient Cable Connector," each assigned to Masimo Corporation and incorporated by reference herein.

The physiological sensor combination **100** is described above with respect to a fold-over that positions the optical sensor components **420-440** so that they extend away from the tissue site. This advantageously allows a smooth surface to be positioned against the tissue site for patient comfort. In another embodiment, however, there is no fold-over **540** and the components **420-440** extend from the substrate toward the tissue site. In yet another embodiment, there is no fold-over and the components **420** are mounted on the substrate side opposite the conductors and utilize substrate feed-throughs to connect with the flex circuit traces **510**. Further, the fold-over **540** is described above as positioning the emitter **420** and detector **430** over substrate apertures **520** (FIG. 5). In an alternative embodiment, the fold-over **540** is skewed so that the emitter **420** and detector **430** are positioned away from the substrate so that no apertures are necessary.

FIG. **4** illustrates a circuit diagram for a physiological sensor combination **100** having a biopotential sensor circuit **401** and an optical sensor circuit **402**. The biopotential sensor circuit **401** has an electrode

array **410**, which is placed on well-separated skin areas. In one embodiment, a first electrode **414** is placed on a temple area **492** and a second electrode **418** is placed on a forehead area **494**. A ground electrode **412** is also placed on the forehead area **494** near the second electrode **418**. Each electrode of the array **410** provides a pinout to a connector **140**. The connector **140** provides sensor input to a monitor. The electrodes placed on the patient's head transmit EEG signals to a monitor, which may include a separate digitizer located near the patient to reduce electrical noise. The difference in potential between the first electrode **414** and second electrode **418** reflects primarily a far-field electrical source, i.e. the EEG from the distant brain cortex, and not a near-field electrical source, such as transdermal nervous stimulation of muscle. The monitor filters the EEG data, analyzes it for artifact and extracts characteristic features from the complex signal to provide pattern recognition of changes over time.

Also shown in FIG. **4**, the optical sensor circuit **402** has an emitter **420**, a detector **430** and an information element **440**. The emitter **420** includes both a red LED (light emitting diode) and an infrared (IR) LED in a back-to-back arrangement. In alternative embodiments, the red and IR LEDs are arranged in three-wire, common anode or common cathode configurations, as is well-known in the art. The detector **430** is a photodiode. The LEDs **420** and photodiode **430** are located on the skin in close proximity, such as on a forehead area **498**. In this manner, the LEDs emit light into the blood vessels and capillaries underneath the skin, and the photodiode **430** is positioned to detect the LED emitted light reflected from the skin tissues. The emitter **420** and detector **430** provide pinouts to the connector **140**, which provides a sensor input to a monitor. The monitor determines oxygen saturation by computing the differential absorption by arterial blood of the two wavelengths of light projected into the skin from the emitter **420**, as is well-known in the art. The monitor provides LED drive current, which alternately activates the red and IR LEDs. The detector **430** uses a single photodiode that responds to both the red and infrared emitted light and generates a time-division-multiplexed ("modulated") output signal to the monitor, corresponding to the red and infrared light energy attenuated by absorption and reflection from the patient's tissue. The monitor has front-end circuitry for amplification, filtering and digitization of the detector signal. The monitor also has a signal processor that calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio.

Further shown in FIG. **4**, the optical sensor circuit **402** may have an information element **440**, such as a resistor configured in parallel with the emitter **420** LEDs. The information element **440** can be read by the monitor and used to determine such things as LED wavelength, sensor type or manufacturer. Information elements and monitor reading of information elements are described in US Patent No. 6,011,986, referenced above. Advantageously, although associated with the optical sensor circuit **402**, the information element **440** can be used to designate information regarding the biopotential sensor portion of the physiological sensor combination **100**. For example, the information element **440** can specify the number of electrodes as well as the electrode locations on the head.

FIG. 5 illustrates a flexible circuit 500 for a physiological sensor combination 100. The flexible circuit 500 has a substrate 504, traces 510, electrodes 410, pinouts 530 and apertures 520. Conductors are deposited and/or etched on a circuit side 502 of the substrate 504 in a pattern to form the traces 510, electrodes 410 and pinouts 532, as is well known in the art. In one embodiment, the substrate 504 is a flexible polyester film and the conductors are silver/silver-chloride. In another embodiment, the conductors are copper. The components 420-440 attach to the flexible circuit 500 and are electrically connected to the traces 510, such as with solder. The fold-over 540 is configured so that the emitter 420 and detector 430 align with the corresponding apertures 520.

FIG. 6 illustrates a physiological sensor combination 600 having a biopotential sensor 610 and an optical sensor 660. The biopotential sensor 610 is configured as described with respect to FIGS. 3-5, above, except that the physiological sensor combination 600 has a connector 620 that is dedicated to the biopotential sensor 610 rather than being shared with the optical sensor 660. The optical sensor 660 also is configured as described with respect to FIGS. 3-5, above, except that a connector 670 is dedicated to the optical sensor 660 rather than being shared with the biopotential sensor 610. Further, the optical sensor 660 has a single fold-over (not visible) on which is mounted the emitter 420 (FIG. 4) and detector 430 (FIG. 4) rather than having a separate fold-over 540 (FIG. 3A) for each.

FIG. 7 illustrates a physiological sensor combination 700 having a biopotential sensor 710 and an optical sensor 760. The biopotential sensor 710 is configured as described with respect to FIG. 6, above. The optical sensor 760 also is configured as described with respect to FIG. 6, above, except that the flexible circuit 500 (FIG. 5) is double-sided, i.e. the traces 510 (FIG. 5) associated with the biopotential sensor 710 are on the side facing the patient's skin when applied, and the traces 510 (FIG. 5) associated with the optical sensor 760 are on the side away from the patient's skin when applied. As a result, the connector 770 is dedicated to the optical sensor 760 and has pinouts 772 facing away from the patient's skin when applied. Further, the optical sensor 760 does not have a fold-over 540 (FIG. 3A). Rather, the optical sensor components 420-440 (FIG. 4) are mounted on the flexible circuit side away from the patient's skin.

A physiological sensor combination is described above with either a shared patient cable connector or a patient cable connector dedicated to each sensor. One of ordinary skill will recognize that either connector configuration will allow the sensor to communicate with a single monitor that analyzes and displays multiple physiological parameters or, alternatively, multiple monitors that are dedicated to analyzing only related physiological parameters, such as oxygen saturation and pulse rate.

The physiological sensor combination as described above can be cost effectively manufactured, advantageously allowing disposable use. One of ordinary skill in the art will recognize that, however, that the physiological sensor combination as disclosed herein can be similarly applied to construct a reusable sensor combination.

The physiological sensor combination was also described above with respect to a shared substrate. One of ordinary skill in the art will recognize that a physiological sensor combination can be constructed from, for example, a biopotential sensor configured on a first substrate and an optical sensor configured on a second substrate, where the first substrate and the second substrate are joined together during the manufacturing process to form a multilayer substrate or an otherwise integrated substrate incorporating multiple sensors.

Although a physiological sensor combination is described above with respect to a biopotential sensor combined with an optical sensor applied to a patient's head, one of ordinary skill in the art will recognize that a physiological sensor combination may be applied to other tissue sites and utilize other sensor combinations, where there is a need to combine two or more sensors in one to accommodate sensors competing for the same tissue site. For example, a physiological sensor combination may include a noninvasive blood pressure (NIBP) sensor and a pulse oximetry sensor or a NIBP sensor and a respiration rate sensor for monitoring on the forearm or the wrist. As another example, a physiological sensor combination may include two optical sensors and one biopotential sensor applied to the forehead and configured as a pulse oximetry sensor and a EEG sensor, as described above, in addition to a near infrared spectroscopy sensor for measuring cerebral tissue oxygenation.

A biopotential sensor as described above could be used in conjunction with a depth of anesthesia monitor that uses not just passive EEG, but also active EEG. That is an Evoked Potential EEG can be used, where some kind of sound is played and changes in EEG are observed as the patient goes into consciousness.

A physiological sensor combination has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

WHAT IS CLAIMED IS:

1. A physiological sensor combination comprising:

a flexible substrate configured to attach to a tissue site;

a plurality of sensors disposed on said substrate and adapted to provide a corresponding plurality of physiological signals, each of said signals responsive to at least one of a plurality of physiological parameters; and

a plurality of conductors disposed on said substrate between said sensors and at least one connector,

said at least one connector configured to communicate said signals to at least one monitor so as to derive a plurality of measurements of said parameters.

2. The physiological sensor combination according to claim 1 wherein said sensors comprise:

a plurality of electrodes disposed on said substrate, each of said electrodes adapted to be in electrical communication with said tissue site and electrically connected to at least one of said conductors; and

an emitter and a detector mounted to said substrate and electrically connected to at least one of said conductors, said emitter adapted to transmit light into said tissue site and said detector adapted to receive reflected light from said tissue site.

3. The physiological sensor combination according to claim 2 wherein:

said substrate has a first side adapted to face toward said tissue site and a second side adapted to face away from said tissue site;

said conductors and said electrodes disposed on said first side; and

said emitter and said detector mounted to said first side.

4. The physiological sensor combination according to claim 3 wherein said substrate comprises a fold-over portion having a circuit side corresponding to said first side, said fold-over portion adapted to fold so that said circuit side is proximate said second side.

5. The physiological sensor combination according to claim 4 wherein said emitter and said detector are mounted to said a fold-over portion.

6. The physiological sensor combination according to claim 5 wherein said substrate defines at least one aperture configured so that said emitter and said detector each align with a corresponding one of said at least one aperture when said fold-over is in a folded position.

7. The physiological sensor combination according to claim 3 further comprising:

a plurality of biopotential sensor pinouts corresponding to said electrodes;

a plurality of optical sensor pinouts corresponding to said emitter and said detector; and

a common connector extending from said substrate, said biopotential sensor pinouts and said optical sensor pinouts each disposed on said common connector.

8. A physiological sensor combination comprising:

a substrate means for combining a first sensor and a second sensor;

a connector means for communicating signals from said first sensor and said second sensor to at least one monitor; and

an identifying means of conveying information about each of said first sensor and said second sensor to said monitor.

9. The physiological sensor combination according to claim 8 further comprising a fold-over means for positioning sensor components so as to extend away from a tissue site.

10. The physiological sensor combination according to claim 9 further comprising an aperture means for providing light communications between sensor components and said tissue site.

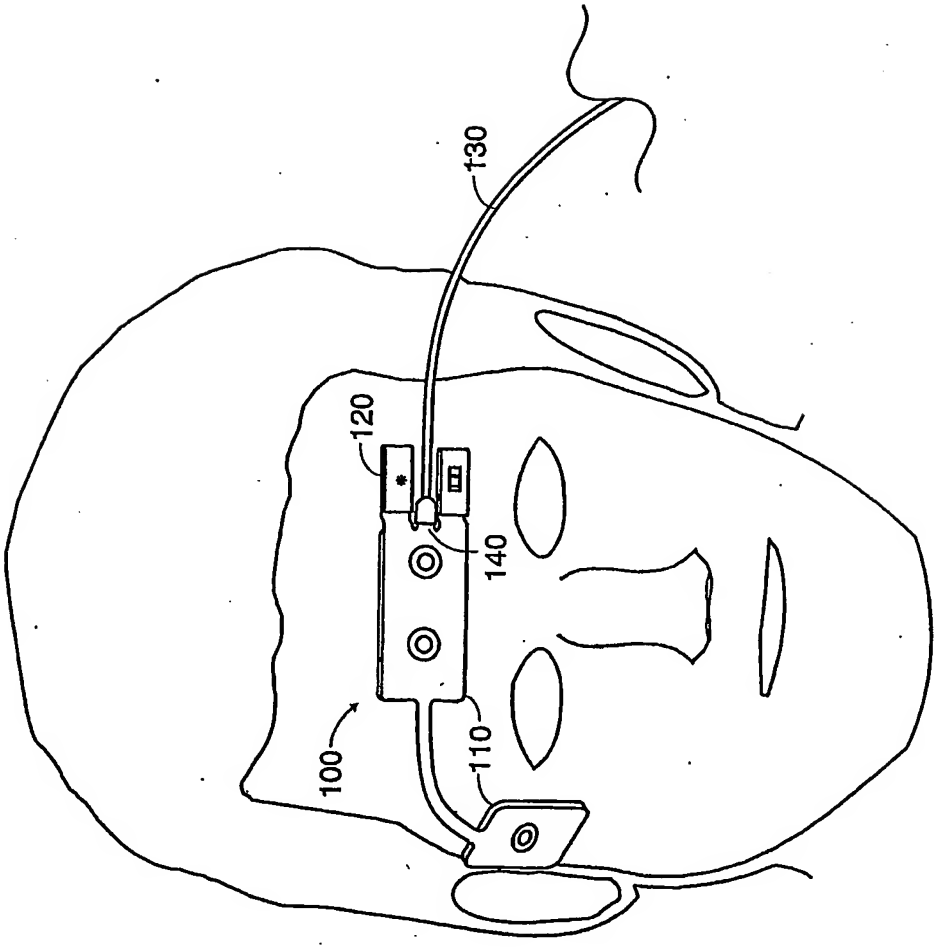


FIG. 1

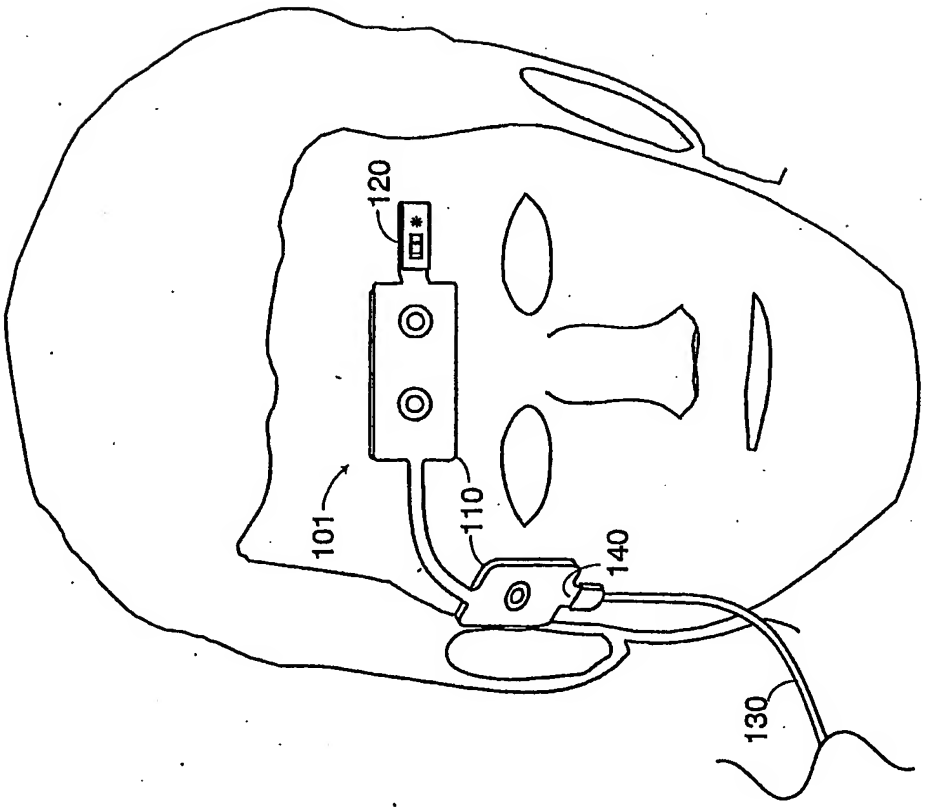


FIG. 2

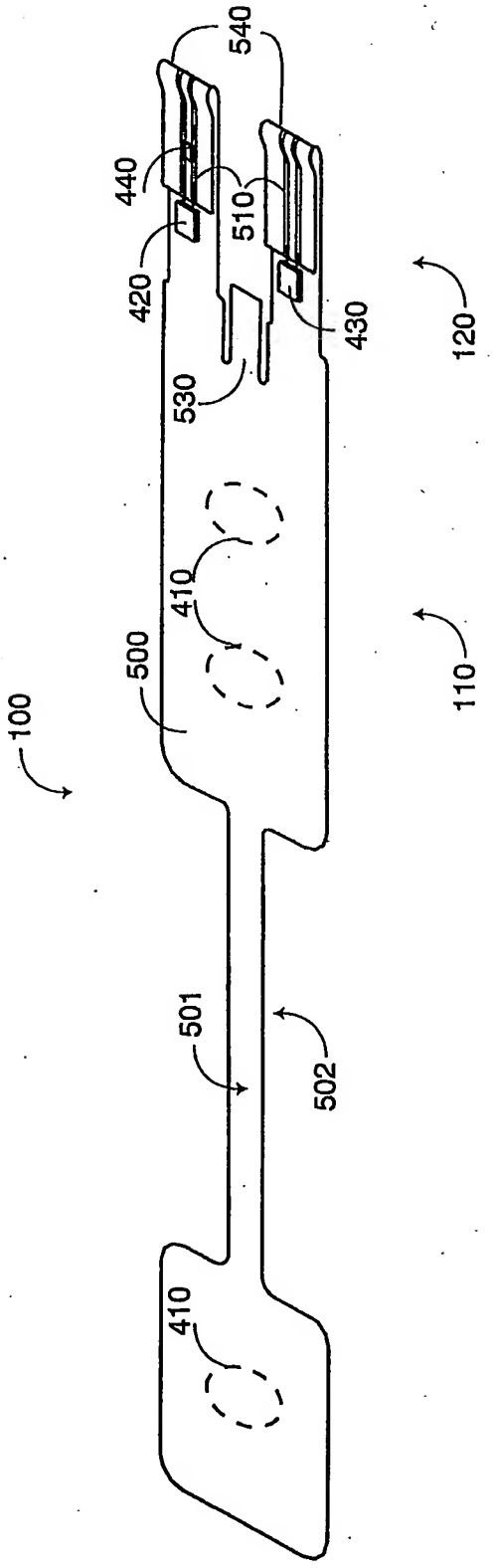
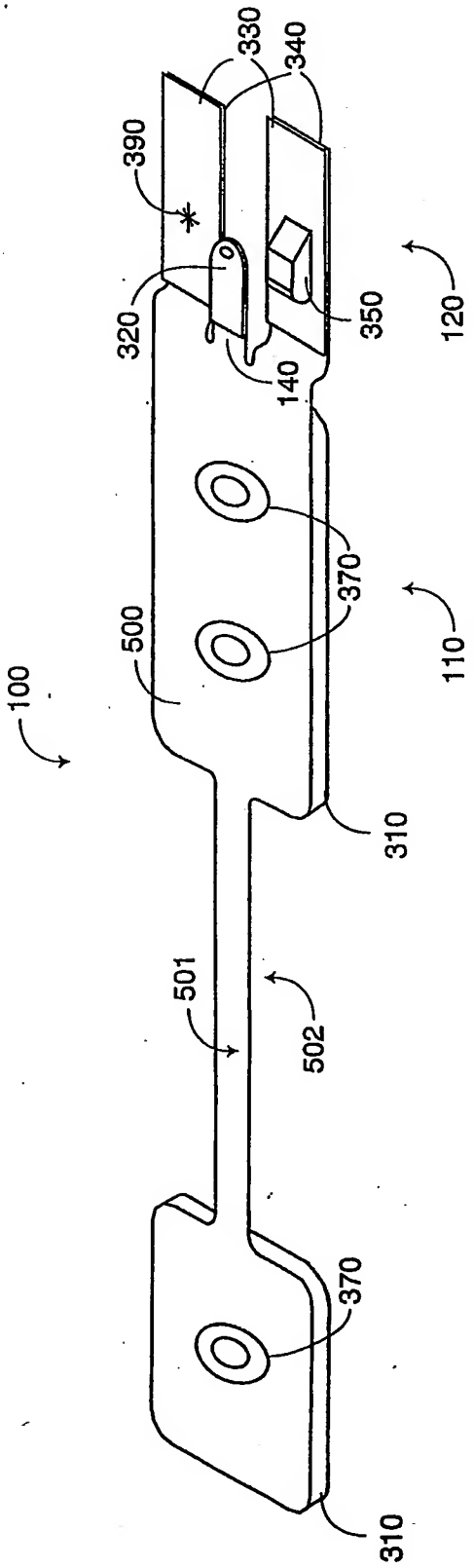

100
500
501
502
410
410
420
440
510
530
540
430
120
110

FIG. 3A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320
330
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350
370
370
120
110

FIG. 3B

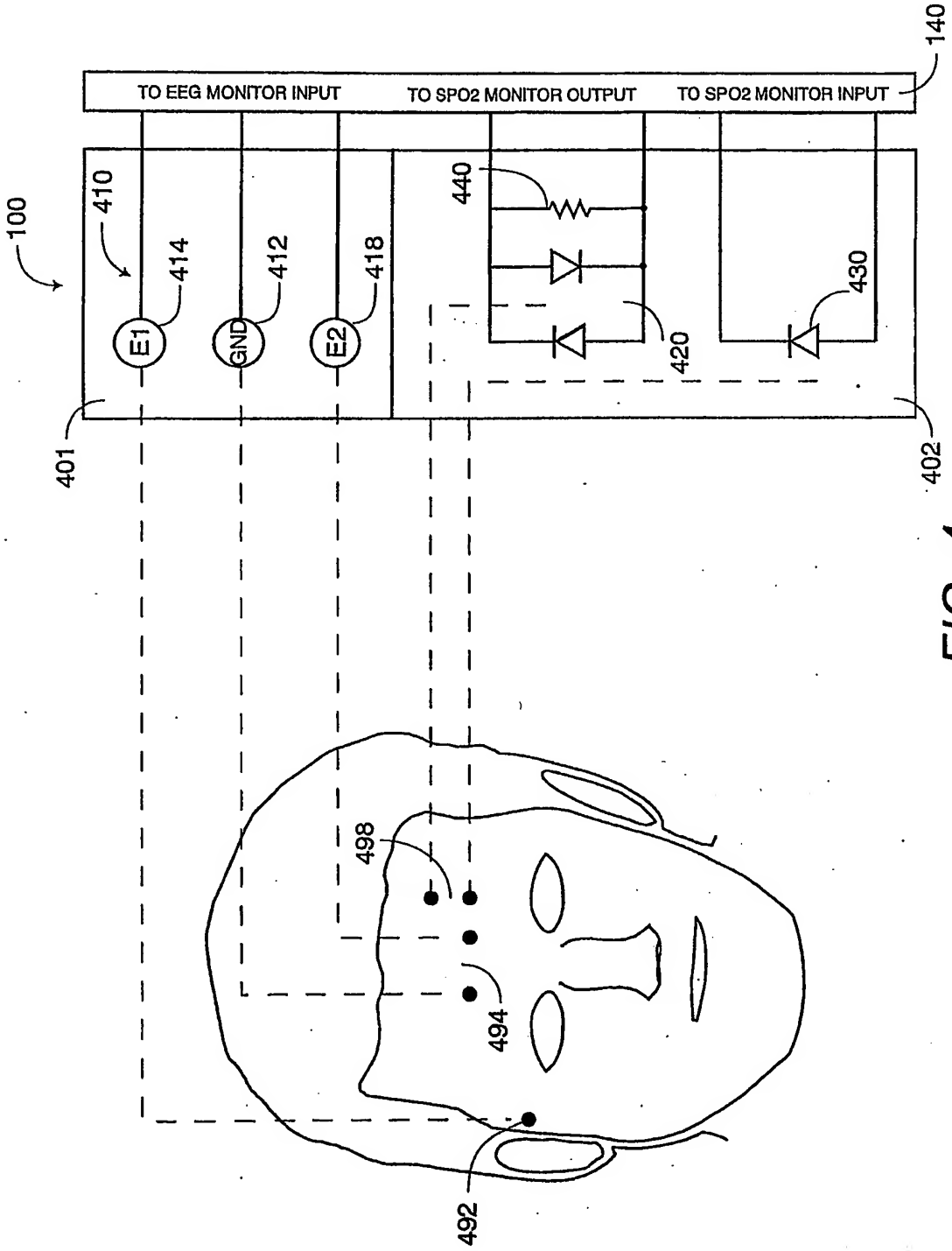
140
TO EEG MONITOR INPUT
TO SPO2 MONITOR OUTPUT
TO SPO2 MONITOR INPUT
100
410
414
412
418
440
430
420
E1
GND
E2
401
402
498
494
492

FIG. 4

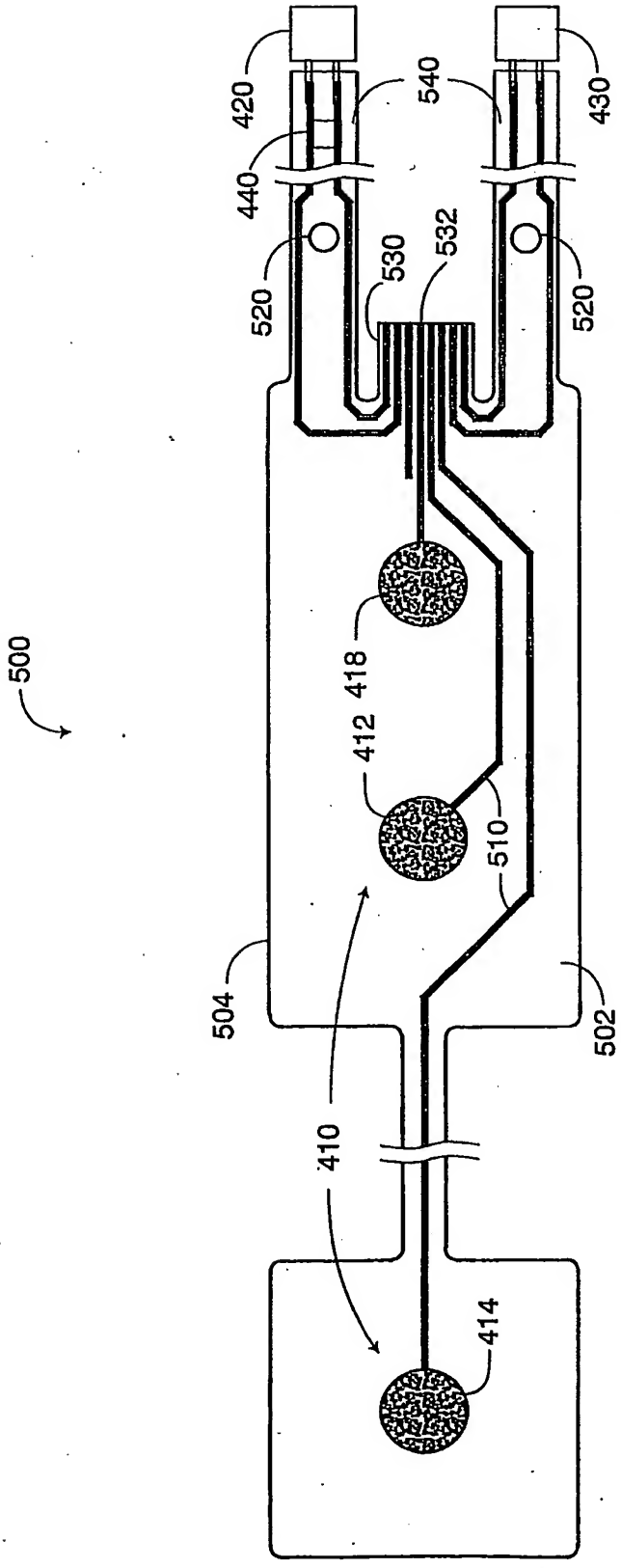

FIG. 5

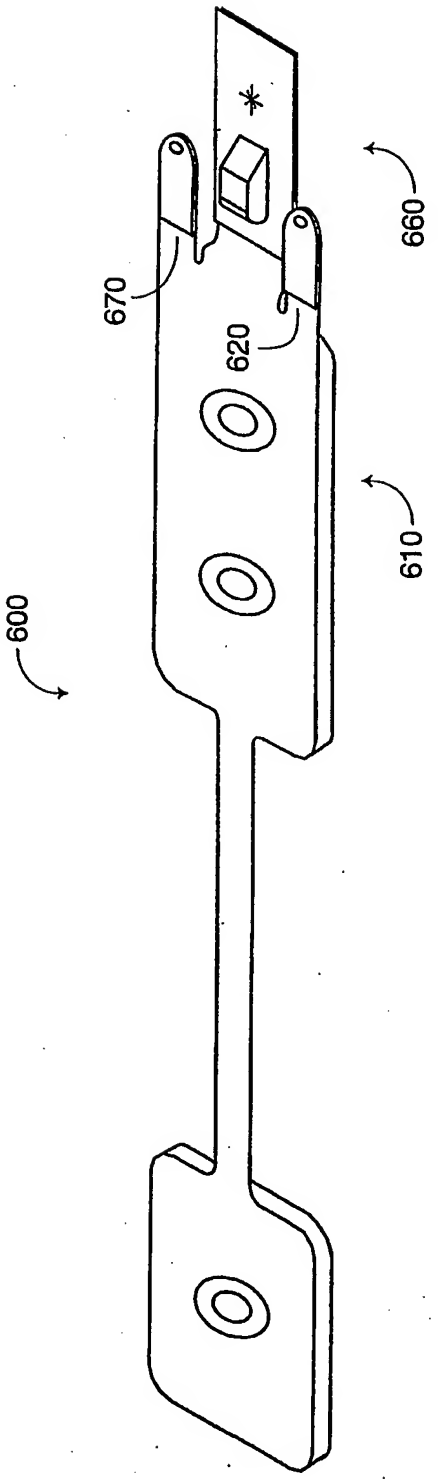

FIG. 6

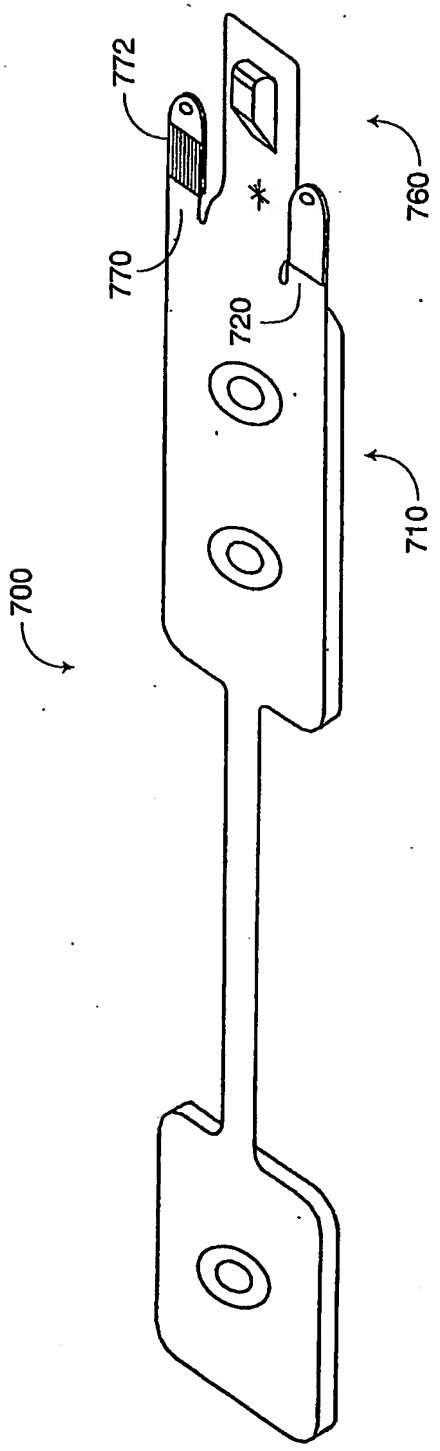

FIG. 7

INTERNATIONAL SEARCH REPORT

Interna pplication No
PCT/US 02/41600

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/0205 . A61B5/0404 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 839 439 A (RUSKEWICZ STEPHEN J ET AL) 24 November 1998 (1998-11-24) abstract; figures 1A,1B column 3, line 1-19 column 3, line 54 - line 62 ---	1-3,8
X	US 5 697 367 A (LEWIS GARY D ET AL) 16 December 1997 (1997-12-16) claims 1,11; figures 1,4 ---	1,2
A	US 6 171 258 B1 (KARAKASOGLU AHMET ET AL) 9 January 2001 (2001-01-09) claims 1,10,12; figure 1 ---	1,2
X	US 6 298 255 B1 (MELO JOAO ET AL) 2 October 2001 (2001-10-02) claim 1; figure 1 ---	1
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 June 2003	24/06/2003

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interna[illegible]pplication No
PCT/US 02/41600

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